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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/935,513	08/22/2001	Harlan Edgar Shannon	X-10576A	9165

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EXAMINER	
WANG, SHENGJUN	

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 06/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/935,513	SHANNON ET AL.	
	Examiner	Art Unit	
	Shengjun Wang	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 January 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-44,60-67 and 81-91* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,6-9,25-31,36-38,40-44,60-67 and 81-91* is/are rejected.

7)☒ Claim(s) *4,5,10-24,32-35 and 39* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1)☐ Notice of References Cited (PTO-892)
2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3)☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4)☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5)☐ Notice of Informal Patent Application (PTO-152)
6)☐ Other: _____.

DETAILED ACTION

Receipt of applicants' remarks submitted January 18, 20005 is acknowledged.

1. The terminal disclaimer filed on January 18, 2005 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of 6,147,072 has been reviewed and is accepted. The terminal disclaimer has been recorded.

2. Claims 4, 5, 10-24, 32-35, and 39 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim Rejections 35 U.S.C. 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 60-67 and 81-91 are rejected under 35 U.S.C. 103(a) as being unpatentable over applicants' admissions in view of Krushinski, Jr., et al. (5,576,321) ('321).

Applicants admit at column 1, lines 42-55 that olanzapine is known to be useful in treatment of psychotic disorders. '321 teaches at column 1 13, line 33 to column 114, line 54 applicants' claimed known compounds of claims 60-67 and 81-91 have known activity in the treatment of psychotic disorders since they are known serotonin reuptake inhibitors and mixed serotonin-norepinephrine reuptake inhibitors. The compositions of claims 60-67 and 81-91 are

drawn to compositions which can be present in a ratio of one to one which are within applicants' claimed ratios.

Therefore, as stated in In re Kerkhoven, 626 F.2d 846, 205 USPQ 1069, at page 1072 (CCPA 1980):

"It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition which is to be used for the very same purpose. In re Susi, 58 CCPA 1074, 1079-80, 440 F.2d 442, 445, 169 USPQ 423, 426 (1971); In re Crockett, 47 CCPA 1018, 1020-21, 279 F.2d 274, 276-277, 126 USPQ 186, 188 (CCPA 1960). As this court explained in Crockett the idea of combining them flows logically from their having been individually taught in the prior art."

In this application the skilled artisan would have been to combine olanzapine with known compounds that are serotonin reuptake inhibitors and mixed serotonin-norepinephrine reuptake inhibitors to treat psychotic disorders since each is known to treat psychotic disorders.

Applicants' data has been reviewed and it is insufficient to determine an unexpected synergistic effect with the combination of known compounds that have a common characteristic. There is a failure to establish a synergistic combination of the claimed active agents as taught by applicants at column 1, lines 43-54 of the subject Reissue application.

The test of obviousness is "whether the teachings of the prior art, taken as a whole, would have made obvious the claimed invention." In re Gorman, 933 F.2d 982, 18 USPQ 2d 1885,

(Fed. Cir. 1991). In view of the above rejection it is deemed that the evidence presented has established a prima facie case of obviousness is presented.

Claims 1-3, 6-9, 25-31, 36-38, 40-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mayer et al. (WO 96/07412, IDS) in view of Nicholas et al. (IDS).

5. Mayer et al. teaches a method of alleviating pain comprising coadministering an non-narcotic analgesic such as NSAID or acetaminophen and an analgesia enhancing amount of non-toxic antagonist for N-methyl-D-aspartate receptor or nontoxic substance that block a major intracellular consequence of N-methyl-D-aspartate receptor activation. Mayer et al. teach that a broad spectrum of non-toxic substance may be used as analgesia enhancers. Particular mentioned are tricyclic antidepressant drugs, such as clozapine. The amount of the nontoxic substance may be determined experimentally by those skilled in the art. See, particularly, pages 3-12.

6. Mayer et al. do not teach expressly the employment of olanzapine as the non-toxic substance.

7. However, Nicolas et al. disclosed that olanzapine is a known antipsychotic agent that functions similarly to clozapine. See, particularly, pages 545and ~~pages~~ 550.

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to use olanzapine as the non-toxic substance in Mayer's method, and make a composition comprising both known NSAID herein and olanzapine.

A person of ordinary skill in the art would have been motivated to use olanzapine as the non-toxic substance in Mayer's method, and make a composition comprising both known NSAID herein and olanzapine because olanzapine is known to function similarly to clozapine, and such

type of agents are known to enhance analgesia effects of NSAID. Further, The optimization of a result effective parameter, effective amounts of olanzapine for enhancing the analgesia effects, is considered within the skill of the artisan. See, In re Boesch and Slaney (CCPA) 204 USPQ 215.

Response to the Arguments

Applicants' remarks submitted January 18, 2005 have been fully considered, but are not persuasive.

Applicants argue that it would have not been obvious for one of ordinary skill in the art to combine two psychotropic agents, citing Preshorn et al. The arguments are unpersuasive. Note, Krushinski, Jr., et al. (5,576,321) expressly teach the combination of the pyschotropic drugs herein with other drugs. It has also known in the art that olanzapine is an atype of antipsychotic agents (see Nicholas et al. IDS). Preshorn et al. merely provide a general guide line for copharmacy in psychiatry and provide no evidence that olanzapine, an atypical antipsychotic agent, and other agents herein employed should not be employed together.

8. Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on January 21, 2005 and March 29, 2005 prompted the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 609(B)(2)(i). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang whose telephone number is (571) 272-0632. The examiner can normally be reached on Monday to Friday from 7:00 am to 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SHENGJUN WANG
PRIMARY EXAMINER

Shengjun Wang
Primary Examiner
Art Unit 1617